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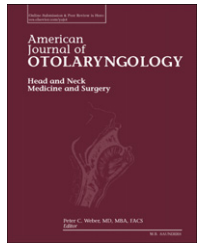

Placement of a 16-French voice prosthesis at the time of secondary tracheoesophageal voice restoration

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ARTICLE INFO

Article history:
Received 4 December 2014

ABSTRACT

Purpose: Tracheoesophageal voice restoration (TEVR) has traditionally been described with fistula tract creation, catheter placement, and prosthesis placement. Prosthesis placement at the time of tracheoesophageal puncture (TEP) utilizing 20-French prostheses has been previously described. Smaller initial prostheses may allow fluent speech with reduced long-term complications, such as widening of the fistula and peri-prosthesis leakage. This study evaluates the safety and efficacy of the 16-French prostheses placement at the time of secondary TEP.

Methods: All cases of 16-French tracheoesophageal voice prosthesis (TEVP) placement at the time of secondary TEP were reviewed from 1/2011 through 12/2013 at a large academic medical center. Perioperative complications attributable to device placement were recorded, including inability to place prosthesis, intraoperative complications, post-operative infection, prosthesis dislodgement, prosthesis leakage, and inability to obtain voice.

Results: Twenty-one patients received placement of a 16-French TEVP at the time of secondary TEP. All prostheses were placed without intraoperative complications. The proportion of patients who had minor complications within the first postoperative month was 23.8%, including leakage through the prosthesis (3 of 21), granulation tissue near the prosthesis (1 of 21), retained sheath (1 of 21) and prosthesis displacement (1 of 21). Leakage and displacement were addressed with change and replacement, respectively. Fluent voicing was achieved in 85.7% patients, with a median time to voicing of 18.5 days.

Conclusions: Placement of 16-French TEVPs is effective and safe, with an acceptable rate of minor complications attributable to the prosthesis. Therefore, a smaller prosthesis may be primarily placed at the time of secondary TEP and is our preference.

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http://dx.doi.org/10.1016/j.amjoto.2015.01.026
0196-0709/

1. Introduction

Tracheoesophageal voice restoration (TEVR) is currently the preferred surgical method of alaryngeal speech rehabilitation. It consists of the creation of a fistula between the esophagus and the trachea, with subsequent placement of a one-way valve to allow airflow from the trachea into the esophagus. The resulting vibration of the pharyngo-esophageal mucosa allows for voice production.

Since its first inception by Singer and Blom [1] in 1980, TEVR has evolved significantly. Originally, the tracheoesophageal puncture (TEP) was performed as a secondary procedure ("secondary TEP"), usually completed weeks to months after total laryngectomy. As surgeons gained more experience with TEVR, TEP at the time of laryngectomy ("primary TEP") was also shown to be safe and effective [2]. In both of these methods, a rubber catheter was used in the surgically created fistula to allow for healing before insertion of the prosthesis. In subsequent years, it was shown that immediate placement of the tracheoesophageal prosthesis (TEVP) at the time of primary or secondary puncture was comparably safe relative to delayed prosthesis placement [3–6]. Immediate prosthesis placement has the potential benefits of fewer required procedures, no need for catheter management or potential dislodgement, a more natural orientation of the puncture tract and shorter time to speech acquisition [3–7].

There is debate about the optimal size of the initial TEVP. The 20-French or larger prostheses became widely used in the 1980 and 1990s, as the larger size was felt to allow greater ease of airflow. At the same time, prostheses management evolved, where the prosthesis was left in for longer periods of time, further favoring a larger prosthesis. With the introduction and widespread acceptance of organ preservation protocols based on concurrent chemoradiation therapy, significant detrimental tissue effects manifested at the puncture tract with TEVR; paramount among these is the widening fistula tract. Although studies have suggested that the size of the initial prosthesis placed may not have a significant effect on the puncture tract long-term, there are theoretical benefits to the use of a smaller 16-French prosthesis, which could reduce the risk of an ever-widening fistula, while preserving the ability to upsize to a larger prosthesis if necessary. Previous work from this institution demonstrated the safety and efficacy of 20-French TEVP placement at the time of primary and secondary tracheoesophageal puncture [6,7], however no study has yet focused on immediate placement of smaller prostheses (16-French) at the time of secondary TEP. The objective of the current study is to evaluate the safety and efficacy of immediate placement of a 16-French prosthesis at secondary TEP.

2. Materials and methods

Approval of this study was obtained through the Massachusetts Eye and Ear Infirmary (MEEI) Institutional Review Board (IRB). Medical records were reviewed for all cases of secondary tracheoesophageal puncture (TEP) placement using Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes. Procedures which occurred from May 2011 through May 2013 were reviewed, and only patients who had follow-up at our institution were included. The surgical technique was similar in all cases and has been previously described [7], and is covered here in brief. All procedures were done under general endotracheal anesthesia. A Blom–Singer tracheoesophageal puncture kit was used. Cervical esophagoscopy was done, and the esophagoscope was positioned with the bevel facing anteriorly. The needle was passed through the stoma and was used to puncture the tracheoesophageal party wall; the needle was then visualized through the esophagoscope. A catheter was placed around the needle, and the needle was removed. A soft wire was passed through the catheter and brought to the proximal end of the esophagoscope. The tract was dilated with a dilating catheter. A 16-French TEVP was placed over the wire and was sewn to the catheter, and was delivered through the puncture tract. The suture, catheter, and wire were removed once the correct position was verified.

Demographic information, medical history, radiation history, comorbidities, operative data, and complications were recorded. Complications attributable to device placement were categorized as intraoperative and postoperative, with attention paid particularly to complications within 1 month of the procedure. Minor complications included inability to place prosthesis during procedure, postoperative infection, prosthesis dislodgement, and leakage around or through the prosthesis. Major complications included stroke, cardiac events, pneumonia, sepsis, and death.

Time to voice fluency was also recorded as a primary outcome. Voice was assessed by certified speech and language pathologists (CCC-SLPs), and was indicated on each postoperative visit on a four-point scale ("excellent", "good", "fair", "poor"). Scores of "excellent" or "good" with easy production of speech were recorded as "fluent." Voice outcomes were recorded from first postoperative visit until the final visit present in the medical record.

Data were analyzed with Microsoft Excel®. Standard descriptive statistics were reported, including mean and median values to estimate the central tendency of the data.

3. Results

Twenty-one patients with 16-French TEVPs placed at the time of secondary tracheoesophageal puncture were included in this study. All patients had previously undergone total laryngectomy for cancer, 14 of which (66.7%) were salvage operations after chemoradiation failure. More than half of these (61.9%) were performed in the final year of inclusion. All prostheses were 16-French in diameter, and the majority of these were 12 mm in length, although 8 mm, 10 mm, and 20 mm lengths were each used once in this series.

There were more men than women in the cohort, with a mean age of 66.2 years (see Table 1). Patient comorbidities were notable for 16 patients (76.2%) with at least one significant comorbidity (diabetes, immunodeficiency, vascular disease, hypothyroidism, cardiac or pulmonary disease). Seventeen patients (81.0%) underwent preoperative radiation therapy before placement of the TEVP. Two patients developed recurrent disease during follow-up. Average follow-up time was approximately 14.9 months (range 2.6 to 29.2).